P980052

P980052 SUMMARY OF SAFETY AND EFFECTIVENESS

TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System

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1. GENERAL INFORMATION

Device Generic Name:	Total Temporomandibular Joint Prosthesis
Device Trade Name:	TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis
Applicant's Name and Address:	TMJ Concepts 4750 Calle Quetzal Camarillo, CA 93012
Premarket Approval (PMA) Number:	P980052
Date of Panel Recommendation:	May 10, 1999
Date of Notice of Approval to the Applicant:	July 2, 1999

2. INDICATIONS FOR USE

The TMJ Concepts Patient-Fitted Temporomandibular Joint (TMJ) Reconstruction Prosthesis is intended to be used for the reconstruction of the temporomandibular joint. It is indicated for patients with one or more of the following conditions:

- Inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment
- Recurrent fibrous and/or bony ankylosis not responsive to other modalities of treatment
- Failed tissue graft
- Failed alloplastic joint reconstruction
- Loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion

3. CONTRAINDICATIONS

The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System should not be used for patients with one or more of the following conditions:

- Active or suspected infections in or about the implantation site
- Uncontrollable masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and loosening of screws
- Known allergy to any of the component materials

4. WARNINGS

General

Do not use product from damaged or open packaging.

Warnings Specific to Anatomical Bone Models

The bone model is provided **CLEAN AND NON-STERILE** and **IS NOT INTENDED TO BE STERILIZED.** No sterilization processes have been demonstrated to produce adequate bone model sterility assurance levels. Sterilization processes may have detrimental effects on the accuracy and integrity of the model.

Implants should not be placed in contact with bone model surfaces nor should the model be introduced into the sterile field at the time of surgery due to the possibility of contamination from residual substances on the model.

Warnings Specific to TMJ Implant Components

TMJ implant components are provided **CLEAN AND NON-STERILE** and no additional cleaning prior to sterilization is needed.

TMJ implant components are intended to be repackaged and sterilized utilizing ethylene oxide (EtO) gas sterilization. (See the section titled STERILIZATION INSTRUCTIONS FOR TMJ IMPLANT COMPONENTS elsewhere in this product insert.)

DO NOT STEAM STERILIZE THE GLENOID FOSSA COMPONENT AS THE HIGH TEMPERATURE MAY DAMAGE THE PLASTIC PORTION OF THE IMPLANT.

TMJ implant components are designed to accommodate a patient's unique anatomy and their implanting surgeon's pre-operative plans using an anatomical bone model produced from a CT scan. These pre-operative plans include establishing the patient's desired occlusal setting either on the patient prior to their CT scan or on their bone model after it has been produced and may also include modifying the anatomical contours of the model. It is very important that the surgeon accurately reproduce the patient's planned occlusal setting and any anatomical contouring at the time of implantation in order to achieve the intended placement of the implant components.

Bone cement or other grouting agents should not be used when implanting these devices. Safety and efficacy have not been established for the use of bone cement or other grouting agents with these implants.

TMJ implant components are intended to be implanted in matched pairs as provided by TMJ Concepts. Safety and efficacy have not been established for the use of other manufacturers' components, including screws, with these devices.

Warnings Specific to Screws And Instruments

TMJ Fixation Screws are provided **CLEAN AND NON-STERILE** and require no additional cleaning prior to sterilization.

Single Use TMJ Fixation Instruments (see table below) are provided **CLEAN AND NON-STERILE** and require no additional cleaning prior to sterilization.

Reusable TMJ Fixation Instruments (see table below) are provided **CLEAN AND NON-STERILE** and should be cleaned and sterilized prior to each use.

Instrumentation

Part Number	Description	Use
60-0100	Quick-Connect Instrument Handle	Reusable
60-0110	Driver Blade	Reusable
60-0120	Implant Stabilizer	Reusable
60-0130	Mandibular Forceps	Reusable
60-0200	Fossa Seating Tool	Reusable
60-0300	Drill Guide	Reusable
60-0420	Pilot Drill for 2.0mm Screws	Single Use
60-0423	Pilot Drill for 2.3mm Screws	Single Use
60-0500	Sterilization Case Lid	Reusable
60-0510	Sterilization Case Screw Base	Reusable
60-0520	Sterilization Case Instrument Base	Reusable

5. PRECAUTIONS

General

It is the responsibility of each surgeon using this product to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedures and the potential complications that may occur in each specific case. The benefits of the surgical procedure may deteriorate over time and no longer meet the patient's or surgeon's expectations necessitating additional or alternative procedures to be performed. Revision implant surgery is not uncommon, therefore, the surgeon must balance many considerations to achieve the best long term result for each patient.

Patients should be advised of the limitations of the implant and instructed to adjust their activities accordingly.

Special attention should be paid to patient selection. Careful evaluation should be made of patients with disorders that might interfere with their ability to comply with the limitations and precautions necessary to achieve beneficial outcome from this implant.

Precaution Specific to Anatomical Bone Models

The bone model contains fragile features. Handle with care.

Precautions Specific to TMJ Implant Components

These implants contain articulating surfaces that may become damaged if mishandled. Any damage to these surfaces may affect the long-term performance of the implants. Avoid contact with the articular surfaces as much as possible.

Implants should only be handled with blunt, smooth-surfaced instruments to avoid damage. Instruments with teeth, serrations, or sharp edges should not be used.

Precautions Specific to Screws

Always place screws into proper locations in the sterilization case for sterilization.

Screws should only be handled with blunt, smooth-surfaced instruments to avoid damage. Instruments with teeth, serrations, or sharp edges should not be used.

Precautions Specific to Instruments

A surgical technique describing the use of the instruments is available. The surgeon should be familiar with the application of the instruments prior to use.

Specialty instruments should never be used to perform tasks for which they are not specifically designed. Misuse of an instrument may result not only in damage to the instrument but also trauma to the patient or operating room personnel.

Avoid storing or transporting instruments in contact with one another as damage may occur.

Use care in handling instruments with cutting edges, points, sharp corners, and hinges as they may cause injury and/or damage surgical gloves compromising sterility.

Do not use instruments that have been damaged. Damaged instruments should be replaced before further use. Do not attempt to straighten bent instruments as this may compromise the strength of the instrument and lead to subsequent failure or injury.

6. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Complications may occur following placement of TMJ implants and may require further treatment. See the system product insert label and the clinical section of this summary for specific adverse events which have been seen during the clinical use of TMJ Concepts Patient-Fitted TMJ Reconstruction Prostheses. The occurrence of a complication may be related to or influenced by the prior medical conditions of the patient. These complications include but are not limited to:

- Infection
- Post-operative pain, swelling, bruising, jaw muscle spasm, or hematoma formation
- Chronic or recurring pain
- Peripheral neuropathies
- Loss of joint mobility due to the development of adhesions, heterotopic bone, or ankylosis
- Ear problems, including inflammation of the ear canal, middle or inner ear infections, perforation of the ear drum, temporary or permanent hearing loss, ringing in the ears, and equilibrium or eustachian tube problems
- Dental malocclusion requiring bite adjustment, orthodontia, or reoperation
- Resorption or erosion of the glenoid fossa, mandible, or surrounding tissues
- Foreign body or allergic reaction to implant components
- Wear, displacement, breakage, or loosening of implant components
- Deleterious effects to the contralateral joint when implant placed unilaterally

7. DEVICE DESCRIPTION

The Patient-Fitted TMJ Reconstruction Prosthesis is comprised of a mandibular component and a glenoid fossa component that have been customized for the patient identified on the front of the product insert.

The system also includes TMJ Fixation Screws, TMJ Fixation Instruments, and an Anatomical Bone Model.

All prosthesis materials comply with the indicated ASTM surgical implant standards.

The TMJ implant mandibular component is comprised of a condylar head fabricated from cobalt-chromium-molybdenum alloy (ASTM F1537) and a mandibular body fabricated from titanium 6Al-4V ELI alloy (ASTM F136).

The TMJ implant glenoid fossa component is comprised of a fossa bearing fabricated from ultra-high-molecular-weight polyethylene (ASTM F648) and a mesh backing fabricated from unalloyed titanium (ASTM F67 and F1341).

The TMJ Fixation Screws are fabricated from titanium 6Al-4V ELI alloy (ASTM F136) and are specifically designed for use in the fixation of Patient-Fitted TMJ Reconstruction Prostheses.

The TMJ Fixation Instruments are specifically designed for use in the implantation of Patient-Fitted TMJ Reconstruction Prostheses and TMJ Fixation Screws. Pilot drills are labeled for single use, and all other instrumentation is labeled as reusable. For a list of the instrumentation, see the table at the end of the WARNINGS section.

The Anatomical Bone Model is produced from a CT scan of the patient's mandible and maxilla and is intended to be used by the surgeon as an anatomical reference in planning and performing the implantation of Patient-Fitted TMJ Reconstruction Prostheses.

These products and their packaging contain no latex materials.

8. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative practices and procedures, depending on individual circumstances, include reconstruction of the TMJ using autogenenous or allogeneic tissue grafts of bone, soft tissue, or cartilage or using another available implant.

9. MARKETING HISTORY

TMJ Concepts (Camarillo, CA) began marketing these implants under 510(k) Premarket Notification K954224 in December 1997. Prior to the 510(k), these implants were placed on the market by Techmedica, Inc. (Camarillo, CA) from January 1989 to September 1993 without such a notification because the company believed them to be custom devices. The application for this PMA was submitted on January 6, 1999, in response to the publication of the final rule in the Federal Register of December 30, 1998, requiring submission of PMA applications for total temporomandibular joint prostheses in accordance with section 515(b) of the Food Drug and Cosmetic Act.

10. SUMMARY OF PRECLINICAL STUDIES

A. Mandibular Component Fatigue Testing. Six test specimens were compressively loaded in an anatomic orientation. Loads were cycled from 667N (150 lbf) to 30N (7 lbf) at 12Hz for 10 million cycles. Literature estimates the maximum clinical load to be 15 to 300 lbf with the highest loads from bruxing or grinding. Patients who brux or grind are not to be implanted with this device. Implantation of the device requires loss of some muscle attachment which would reduce the highest loads possible to half of the maximum or less. Therefore the 150 lbf maximum load was considered to be adequate. No gross failures occurred and no cracks were detected under Zyglo penetrant inspection.

B. Mandibular Component Static Strength Testing. Six test specimens were set in an anatomic orientation and fixed in the testing apparatus. Parts were loaded until yielding or fracture occurred, and the peak load was recorded. All parts yielded with an average yield strength of 3514N (790 lbf). This is much higher than any load estimated for clinical usage.

C. Wear Testing. A mechanical joint simulator was used to determine the wear performance of these TMJ implant components. Six glenoid fossa and mandibular component pairs underwent five million cycles under a 9kg constant load in a bovine serum environment. Direct measures of the resultant wear track were obtained. Average penetrative and volumetric wear rates were determined to be 0.010mm/million cycles and 0.39mm^3/million cycles. From this joint simulation, the minimum mechanical wear life of the prosthesis was estimated to be in excess of 86 million cycles. Literature shows the average number of chewing cycles in a year to be between 1 and 10 million cycles. The joint simulator is an adequate, if simplified, representation of the clinical situation, and the wear life estimated would be adequate to prevent a frequent need to revise the implant for wear.

D. Fossa Component Bond Testing. Ten fossa components manufactured at the processing parameter extremes were loaded in shear until failure occurred. A minimum allowable shear strength of 75 lbf was established. Fossa component shear strengths averaged 345.3 lbf which exceeds the minimum allowable strength by a 4.6 factor of safety. This safety factor is adequate for temporomandibular joint devices.

11. SUMMARY OF CLINICAL STUDIES

A total of 347 patients have received the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis. Clinical Study #1 prospectively evaluated 363 joints placed in 215 patients by 16 different surgeons, and the Postmarket Surveillance Study prospectively evaluated the remaining 132 patients (218 joints). Study #2 evaluated a subset of Study #1. Studies #1 and #2 were not sponsored by TMJ Concepts.

Pre-operative data and post-operative follow-up data were collected using a standardized data collection format. Subjective data related to pain, function of the lower jaw, and diet were obtained using a 55mm length visual analogue scale. The pain scale ranged from "no pain" at 0mm to "severest pain" at 55mm. The function scale ranged from "no loss" at 0mm to "cannot function" at 55mm. The diet scale ranged from "no restriction" at 0mm to

"liquids only" at 55mm. Objective measurements of mandibular range of motion were made directly on the patients. These measurements, recorded in millimeters, included maximum interincisal opening and left and right excursion. Left and right excursions did not change significantly over time, and are not included with the following tables.

A. Clinical Study #1

This prospective study evaluated 365 joints placed in 215 patients by 16 different surgeons between 1989 and 1993. Data for every patient was not available for every time point. Statistical analysis of the study was inconclusive due to the missing data points.

The following table is the adverse events information for Clinical Study #1.

Adverse Events

Category	Patients (n=215)	Percent
Design complications (components loosened, became dislocated, or did not fit correctly)	13*	6.0%*
Biologic complications (infection or immunologic response)	3	1.4%
Material failures (component breakage)	1	0.5%
Heterotopic bone formation (category is not device-related)	13	6.0%
Patient requested removal of implant with no clinical indications (category is not device-related)	5	2.3%
Total adverse events	35	16.3%
Subtotal device-related adverse events	17	7.9%

* Design complications were related to early implant designs. Changes to quantity and placement of screw holes in mandibular components reduced the incidence of implant loosening.

B. Clinical Study #2

This study evaluated a subset of 111 patients (195 joints) from Clinical Study #1 from 2 surgeons for whom detailed information was available at 2 or more years. Data for every patient was not available for every time point. The number of patients (N) decreased over time due to patients having been lost to follow-up and also due to patients not yet having reached a particular follow-up interval (i.e., patients who only had their implants for a shorter time period and were not lost to follow-up). Of these 111 patients, there were 95 who had data at 3 years or beyond, but all those who did not have complete data at baseline, 1, 2, and 3 years were dropped from the statistical analysis. There were 34 patients who had complete data for pain and function and 33 patients who had complete data for diet and maximum interincisal opening.

The following four tables are the data for all the patients in Clinical Study #2.

Pain Measurements over Time
(scale: 0mm = "no pain" to 55mm = "severest pain")

Month	N	Mean (mm)	S.D. (mm)
0	105	43.3	12.1
2	57	19.2	14.4
4	45	15.0	12.0
6	47	15.8	16.1
8	34	19.6	17.2
12	69	18.5	14.4
24	72	22.0	15.8
36	63	20.3	15.2
48	43	20.6	16.1
60	42	17.6	15.5
72	21	22.5	15.4
84	13	16.5	19.9
96	3	22.2	19.3

Function Measurements over Time
(scale: 0mm = "no loss" to 55mm = "cannot function")

Month	N	Mean (mm)	S.D. (mm)
0	106	40.3	13.2
2	54	19.3	13.5
4	43	16.2	11.9
6	46	17.2	13.7
8	33	16.2	14.0
12	69	19.3	14.6
24	72	22.5	15.3
36	63	19.4	11.4
48	43	23.0	11.7
60	42	20.3	11.2
72	21	25.1	11.6
84	13	20.4	13.4
96	3	21.6	19.7

Diet Measurements over Time
(scale: 0mm = "no restriction" to 55mm = "liquids only")

Month	N	Mean (mm)	S.D. (mm)
0	106	37.6	14.7
2	55	21.4	15.3
4	42	13.4	12.0
6	45	17.8	15.5
8	33	15.9	16.0
12	69	16.8	14.4
24	72	19.6	15.5
36	63	19.2	14.2
48	43	20.9	13.0
60	41	17.6	13.0
72	21	21.0	14.6
84	13	18.9	11.7
96	3	26.0	13.4

Maximal Interincisal Opening Measurements over Time

Month	N	Mean (mm)	S.D. (mm)
0	107	24.6	11.6
2	52	26.5	6.7
4	48	30.9	6.7
6	49	30.7	8.5
8	34	32.2	7.5
12	69	31.7	8.6
24	70	32.6	9.0
36	63	33.3	8.4
48	42	33.0	8.0
60	41	34.5	7.9
72	21	30.2	9.7
84	13	31.8	8.3
96	3	28.3	9.5

The following four tables are the statistical analysis of the cohorts in Clinical Study #2 with complete data at baseline, 1, 2, and 3 years.

Pain Measurements over Time for 34 Patients
(scale: 0mm = "no pain" to 55mm = "severest pain")

Month	Mean (mm)	S.D. (mm)
0	42.4	11.9
12	16.3	13.2
24	21.9	14.9
36	21.1	13.9

Function Measurements over Time for 34 Patients
(scale: 0mm = "no loss" to 55mm = "cannot function")

Month	Mean (mm)	S.D. (mm)
0	38.1	14.9
12	16.9	13.0
24	19.4	14.7
36	18.6	10.2

Diet Measurements over Time for 33 Patients
(scale: 0mm = "no restriction" to 55mm = "liquids only")

Month	Mean (mm)	S.D. (mm)
0	35.2	15.6
12	13.2	11.2
24	17.1	14.3
36	20.5	13.4

MIO Measurements over Time for 33 Patients

Month	Mean (mm)	S.D. (mm)
0	24.8	11.6
12	32.8	7.6
24	33.4	7.4
36	34.1	7.0

Statistical analyses of the cohorts of patients with complete data showed significant decrease in pain, increase in function, decrease in diet restrictions, and increase in maximum interincisal opening. The data from the 215 patients in Clinical Study #1 and the 111 patient subset in Clinical Study #2 showed similar trends in pain, function, diet,

and interincisal opening. The analyzed cohorts in Clinical Study #2 represented approximately 10% of all the patients implanted with this device.

Total patients = 347 (215 + 132 from the Postmarket Surveillance Study)
See subsection C for Postmarket Surveillance Study data.

Adverse events are presented for the 111 patient subset in the tables below. The adverse events data for these patients was updated in April 1999. The data for the remaining 104 patients in Clinical Study #1 was not available after December 1994 when the study ended. The device removal rate due to device-related failure or complication was 2.6%. Adverse events which did not result in device removal occurred in 25.6% of the devices, and one quarter of these were for device-related reasons.

Adverse Events Requiring Device Removal

Category	Patients (n=111)		Joints (n=195)	
	No.	%	No.	%
Device removal due to failure or complication	5*	4.5%	5*	2.6%
Patient requested removal of implant with no clinical indications (category is not device-related)	4	3.6%	8	7.2%
Total adverse events requiring device removal	9	8.1%	13	6.7%
Subtotal device-related adverse events requiring device removal	5*	4.5%	5*	2.6%

* 4 of these 5 devices were removed for mandibular component loosening that was related to early implant designs. Changes to quantity and placement of screw holes in mandibular components reduced the incidence of implant loosening.

Adverse Events Not Requiring Device Removal

Category	Patients (n=111)		Joints (n=195)	
	No.	%	No.	%
Improper fit	3	2.7%	5	2.6%
Dislocation	1	0.9%	2	1.0%
Post-operative infection	3	2.7%	3	1.5%
Other	2	1.8%	2	1.0%
Heterotopic bone formation (category is not device-related)	20	18.0%	38	19.5%
Total adverse events not requiring device removal	29	26.1%	50	25.6%
Subtotal device-related adverse events not requiring device removal	9	8.1%	12	6.2%

C. Postmarket Surveillance Study

This study was initiated as part of the requirements for postmarket surveillance after receiving 510(k) clearance. The prospective study evaluated all patients into whom a device had been implanted since TMJ Concepts began marketing under a 510(k) in December 1997. The data goes up to April 1, 1999. There were 218 joints placed in 132 patients.

87 patients had their 2-month follow-up visit with subjective measures taken. These patients showed a pain decrease to about 1/2 of pre-operative levels. Function increased by approximately a factor of 2, and diet restrictions decreased by roughly 1/3.

86 patients had objective measures taken at 2 months. There was an increase of approximately 25% in maximum interincisal opening, but left and right excursion did not significantly change.

There were no device failures. One mandibular component had to be replaced due to discrepancies between the patient's occlusion at surgery and that of the anatomical bone model.

12. CONCLUSIONS DRAWN FROM STUDIES

Preclinical

The results of the preclinical studies demonstrate that the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis has adequate strength and durability for its intended use. This evaluation was based on clinical models of jaw structure and function.

Safety

The types of adverse events reported in Clinical Study #1, #2, and the Postmarket Surveillance Study and the rate at which they occurred are not unexpected in this compromised patient population with many previous surgeries involving failed tissue grafts and/or failed implants from other manufacturers which may leave behind material particulates.

Efficacy

Clinical Study #2 showed that for the evaluated cohorts of patients with complete data at baseline, 1, 2, and 3 years, the TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis provided statistically significant levels of reduced pain, increased function, improved diet, and increased maximum interincisal opening. Similar trends, although not statistically significant, were observed in the entire patient groups from Clinical Studies #1 and #2 and the ongoing Postmarket Surveillance Study. The analyzed cohorts represented approximately 10% of all the patients implanted with this device. These patients are representative of the target patient population.

13. PANEL RECOMMENDATION

At a May 10, 1999, meeting of the Dental Products Panel, the panel recommended that TMJ Concepts' PMA for the Patient-Fitted TMJ Reconstruction Prosthesis was approvable subject to a number of conditions including the continuation of the Postmarket Surveillance Study as a postapproval study with some slight modifications to the protocol and the agreement that any device removals relating to wear would be analyzed and compared to the preclinical testing. Additional conditions included labeling revisions and the establishment of a patient registry. The panel wished to emphasize that patients with greater than ten surgeries should be informed that implantation of this device has not been shown to decrease pain in the long term. The panel also emphasized that this device is intended for patients with few alternatives for reconstruction. They believed that this implant should therefore not be considered as a primary treatment.

14. FDA DECISION

Reports of significant human experience and nonclinical investigations with the marketed device are sufficient under 21 CFR 860.7 for the purposes of determining safety and effectiveness for preamendments devices. It is reasonable to conclude based on the data received that the benefits of the use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use. CDRH concurred with the panel recommendation except for the establishment of a patient registry. The agency felt a patient registry was not needed because a registry would duplicate much of the work required of companies manufacturing tracked devices under 21 CFR 821.20 and would thus be overly burdensome to these companies.

The applicant has agreed to submit a revised study protocol as a supplement and to perform the requested wear analysis when any device removals relating to wear occur.

FDA inspections completed May 7, 1999, determined the manufacturing facilities to be in compliance with the Quality System Regulations (QSR).

CDRH issued an approval order on July 2, 1999.

15. APPROVAL SPECIFICATION

- Directions for use: See the labeling.
- Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.
- Postapproval Requirements and Restrictions: See approval order.

TMJ CONCEPTS

PATIENT-FITTED TEMPOROMANDIBULAR JOINT RECONSTRUCTION PROSTHESIS SYSTEM

PRODUCT INSERT INFORMATION

CAUTION

United States Federal Law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The Patient-Fitted Temporomandibular (TMJ) Reconstruction Prosthesis is comprised of a mandibular component and a glenoid fossa component that have been customized for the patient identified on the front of the product insert.

The system also includes TMJ Fixation Screws, TMJ Fixation Instruments, and an Anatomical Bone Model.

All prosthesis materials comply with the indicated ASTM surgical implant standards.

The TMJ implant mandibular component is comprised of a condylar head fabricated from cobalt-chromium-molybdenum alloy (ASTM F1537) and a mandibular body fabricated from titanium 6Al-4V ELI alloy (ASTM F136).

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The TMJ Fixation Screws are fabricated from titanium 6Al-4V ELI alloy (ASTM F136) and are specifically designed for use in the fixation of Patient-Fitted TMJ Reconstruction Prostheses.

The TMJ Fixation Instruments are specifically designed for use in the implantation of Patient-Fitted TMJ Reconstruction Prostheses and TMJ Fixation Screws. Pilot drills are labeled for single use, and all other instrumentation is labeled as reusable. For a list of the instrumentation, see the table at the end of the WARNINGS section.

The Anatomical Bone Model is produced from a CT scan of the patient's mandible and maxilla and is intended to be used by the surgeon as an anatomical reference in planning and performing the implantation of Patient-Fitted TMJ Reconstruction Prostheses.

These products and their packaging contain no latex materials.

INDICATIONS FOR USE

The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System is intended to be used for the reconstruction of the temporomandibular joint. It is indicated for patients with one or more of the following conditions:

- Inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment
- Recurrent fibrous and/or bony ankylosis not responsive to other modalities of treatment
- Failed tissue graft
- Failed alloplastic joint reconstruction
- Loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion

CONTRAINDICATIONS

The TMJ Concepts Patient-Fitted TMJ Reconstruction Prosthesis System should not be used for patients with one or more of the following conditions:

- Active or suspected infections in or about the implantation site
- Uncontrollable masticatory muscle hyperfunction (clenching or grinding) which may lead to overload and loosening of screws
- Known allergy to any of the component materials

WARNINGS

General

Do not use product from damaged or open packaging.

Warnings Specific to Anatomical Bone Models

The bone model is provided **CLEAN AND NON-STERILE** and **IS NOT INTENDED TO BE STERILIZED.** No sterilization processes have been demonstrated to produce adequate bone model sterility assurance levels. Sterilization processes may have detrimental effects on the accuracy and integrity of the model.

Implants should not be placed in contact with bone model surfaces nor should the model be introduced into the sterile field at the time of surgery due to the possibility of contamination from residual substances on the model.